ges. 23/8/04

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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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20. Aug. 2004
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PATENTANWÄLTE RECHTSANWÄLTE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	19.08.2004
Applicant's or agent's file reference 100 019 a/ubr	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/09862	27.08.2003	27.08.2002

Applicant
PARI GMBH SPEZIALISTEN FÜR EFFEKTIVE ... et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Schmidbauer, A Tel. +49 89 2399-8222

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100 019 a/ubr	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/09862	International filing date *(day/month/year)* 27.08.2003	Priority date *(day/month/year)* 27.08.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/08		
Applicant PARI GMBH SPEZIALISTEN FÜR EFFEKTIVE ... et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.03.2004	19.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Borowski, A Telephone No. +49 89 2399-2758

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/09862

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-17	as originally filed

Claims, Numbers

1-14, 15 (part), 25 (part), 26-28	as originally filed
15 (part), 16-24, 25 (part)	received on 23.07.2004 with letter of 23.07.2004

Drawings, Sheets

1/6-6/6	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-28
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-28
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1: EP-A-0 507 707 (DIFFUSION TECH FRANCAISE SARL) 7 October 1992 (1992-10-07)
D2: WO 00 51672 A (DJUPESLAND PER GISLE) 8 September 2000 (2000-09- 08)
D3: DE 32 38 149 A (BRUGGER INGE) 19 April 1984 (1984-04-19)

V.1 Claim 1 of the present application does not meet the requirements for inventive step (Article 33(3) PCT).

Document D1, which is considered to represent the most relevant state of the art, discloses a therapeutic aerosol device comprising a nebuliser device (fig. 1 (2)) having an aerosol generator (column 4, line 54 - column 5, line 2) and a pressure connection device (fig. 1 (7)) supplying pressure fluctuations (claim 1) superimposed on the aerosol main flow (fig. 1 (51)) and a nosepiece (Fig. 1 (2b)) for supplying the aerosol into one of two alae of the nose of a patient.

The subject-matter of claim 1 differs from the device disclosed by D1 in that the aerosol device further comprises a flow resistance device to be applied to the other of the two alae.

The problem to be solved by the differentiating feature may therefore be regarded as how to improve a deposition of aerosol particles in the nose and paranasal sinuses.

However, this features has already been employed for the same purpose in a similar aerosol device, see document D2, page 19, line 20 - page 20, line 11. Although the aerosol device disclosed by D2 comprises a nose piece and a flow resistance device (as in claim 1 of the present application) and also a closure unit for causing the closure of the oropharyngeal velum, but claim 1 of the present application according to it's wording (*"Therapeutic aerosol device with..."*) does not exclude a presence of additional parts. Therefore it would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claim 1. The

subject-matter of claim 1 does therefore not involve an inventive step (Article 33(3) PCT).

V.2 Dependent claims 2-28 are also not considered to meet the requirements for inventive step (Article 33(3) PCT), since their additional features are disclosed by documents D1 or D2, with an exception of additional features of claims 2, 7, 12 and 15-17, which would be regarded by a skilled person as a normal design procedure (see D3 for example).

V.3 The independent claim 1 has not been drafted in the two-part form, as normally required by Rule 6.3(b) PCT.

shape with a first area (A-A) with a large diameter and a second diameter (B-B) with a small diameter.

16. Therapeutic aerosol device according to any one of the preceding claims, characterised in that the nebuliser device (1) comprises an air inlet flue (9) and the pressure connection device (25) is intended to supply pressure fluctuations at the air inlet flue (9).

17. Therapeutic aerosol device according to claim 16, characterised in that the pressure connection device (25) comprises a meander-shaped guide (27) for the compressed air.

18. Therapeutic aerosol device according to any one of the preceding claims, characterised in that compressed air is supplied through the pressure connection device (25).

19. Therapeutic aerosol device according to any one of the preceding claims, characterised in that the frequency of the pressure fluctuations lies within the range from 10 to 100 Hz, preferably in the range from 15 to 55 Hz.

20. Therapeutic aerosol device according to any one of the preceding claims, characterised in that the pressure fluctuations are generated by means of a membrane compressor comprising a membrane (21) that seals a pressure chamber (20) in a pressure-tight way and is moved to and fro by a piston rod.

21. Therapeutic aerosol device according to claim 20, characterised in that the pressure chamber (21) comprises a connecting piece (24) for the connection of

a hose line (26) which is connected to the pressure connection device (25) in the nebuliser device.

22. Therapeutic aerosol device according to any one of the preceding claims, characterised in that a sensor device (34, 37, 41) to determine the main aerosol flow or the pressure fluctuations is provided on the flow resistance device (11).

23. Therapeutic aerosol device according to claim 22, characterised in that an evaluation device (35) and a display device (36) are connected to the sensor device (34) to indicate to the patient whether the main aerosol flow or the pressure fluctuations are sufficiently within the area of the flow resistance device (11).

24. Therapeutic aerosol device according to claims 22 or 23, characterised in that the sensor device comprises a movable display element (41) which is arranged in a display section (38) of the sensor device (37) and is moved by the main aerosol flow or the pressure fluctuations.

25. Therapeutic aerosol device according to any one of claims 1 to 23 for the application of one or more of the following substances:

substances with an anti-inflammatory action, for example: betamethasone, beclomethasone, budesonide, ciclesonide, dexamethasone, desoxymethasone, fluoconolone acetonide, flucinonide, flunisolide, fluticasone, icomethasone, rofleponide, triamcinolone acetonide, fluocortin butyl, hydrocortisone aceponate, hydrocortisone buteprate buteprate, hydroxycortisone-17-